EXHIBIT I

LEXSEE 2003 U.S. DIST. LEXIS 5623

IN RE VIROPHARMA, INC., SECURITIES LITIGATION

CIVIL ACTION MASTER FILE NO. 02-1627

UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

2003 U.S. Dist. LEXIS 5623

April 3, 2003, Decided
April 7, 2003, Filed

DISPOSITION: Defendants' motion to dismiss consolidated class action complaint granted in part and denied in part.

CASE SUMMARY:

PROCEDURAL POSTURE: Plaintiffs, purchasers of defendant pharmaceutical company's securities brought the instant a class action securities fraud case against the company and its officers. The purchasers claimed that the company and its officers made materially misleading statements regarding a drug that was developed by the company. The company and its officers moved to dismiss.

OVERVIEW: The purchasers alleged that the statements misled them as to whether a drug to treat the common cold in adults would be approved by the Food and Drug Administration (FDA). When the FDA rejected the drug, the company's stock plummeted. Despite studies that failed to show treatment benefits, the company announced that a later study had proven successful. The purchasers alleged the company and officers breached their duty to not make material misstatements. The court held that several of the allegedly actionable statements were not material. However, the remainder of the alleged statements could not be disregarded as puffery or subjective opinions. Statements regarding the overall efficacy of the drug, the claim that smokers received a decreased benefit when in fact the data showed the drug extended the duration of their colds, and statements that the new drug application was aimed at seeking approval for all adults, could not be simply dismissed as immaterial as the company and officers claimed. The purchasers sufficiently alleged that the company and the officers either knew their statements were false or acted with reckless disregard for the truth of those statements.

OUTCOME: The company's and the officer's motion to dismiss the consolidated class action complaint was granted in part and denied in part.

LexisNexis(R) Headnotes

Civil Procedure > Pleading & Practice > Defenses, Demurrers, & Objections > Motions to Dismiss

[HN1] On a motion to dismiss, a court must accept all of the facts pleaded in a plaintiffs' complaint as true and take all reasonable inferences in favor of a plaintiff. A court is not limited, however, to the four corners of the complaint. A court may consider any document that is explicitly relied upon in the complaint. A court can also consider the text of an undisputedly authentic document that is integral to a plaintiff's claim, even if the document is not attached to or named in the complaint.

Civil Procedure > Pleading & Practice > Defenses, Demurrers, & Objections > Motions to Dismiss
Civil Procedure > Dismissals > General Overview
Evidence > Judicial Notice > Adjudicative Facts > Public Records

[HN2] In addition to documents relied on by a plaintiff in a complaint, regarding a motion to dismiss, a court may can consider materials that are public records and that may be judicially noticed under *Fed. R. Evid. 201*. These materials, however, may only be considered for the limited purpose of showing that a particular statement was made by a particular person. They may not be considered for the truth of the matters stated within them.

Securities Law > Liability > Securities Exchange Act of 1934 Actions > Express Liabilities > Misleading Statements > General Overview

[HN3] To state a claim under S.E.C. Rule 10b-5 promulgated under the Securities Exchange Act of 1934, a plaintiff needs to plead that: (1) a defendant has made a materially false or misleading statement or omitted a material fact necessary to make a statement not misleading; (2) the statement is made in connection with the sale of securities; (3) the statement is made with scienter; (4) the plaintiff reasonably relies on the statement; and, (5) the misstatement proximately causes the plaintiff's injury.

Securities Law > Liability > Securities Exchange Act of 1934 Actions > Express Liabilities > Misleading Statements > General Overview

[HN4] Drug interaction data that is not statistically significant need not be disclosed in order to prevent prior statements about a drug's safety from becoming materially misleading under Rule 10b-5 promulgated under the Securities Exchange Act of 1934.

Securities Law > Liability > Disclosures > Soft Information

Securities Law > Liability > Securities Exchange Act of 1934 Actions > Express Liabilities > Misleading Statements > General Overview

Torts > Intentional Torts > Defamation > Defenses > Fair Comment & Opinion

[HN5] Only misrepresentations that are material are actionable under S.E.C. Rule 10b-5 promulgated under the Securities Exchange Act of 1934. The test for determining the materiality of a statement is whether a reasonable investor would believe that it significantly alters the "total mix" of information available to that investor. Certain types of "soft information" such as statements of subjective opinions and intentions are immaterial as a matter of law. Similarly, the law considers vague and general statements of optimism as mere immaterial puffery. To determine whether a statement is puffery, a court must examine the context in which the statement was made. Classic examples of puff include a broker calling a bond "marvelous," or saying a stock is so "red hot" that the investor "could not lose."

Securities Law > Liability > Disclosures > Forward Looking Statements

Securities Law > Liability > Private Securities Litigation > Safe Harbor Provisions

[HN6] The Private Securities Litigation Reform Act of 1995 provides a safe harbor for forward-looking statements. A forward looking statement is one whose truth or falsity cannot be determined until after the statement has been made. Forward looking statements include: (1) a statement containing a projection of revenues or other financial items; (2) a statement of the plans and objectives of management for future operations, including plans or objectives relating to the products or services of the issuer; (3) a statement of future economic performance; and (4) any statement of the assumptions underlying or relating to the aforementioned statements. 15 U.S.C.S. § 78u-5(i)(1).

Securities Law > Liability > Disclosures > Forward Looking Statements

Securities Law > Liability > Private Securities Litigation > Safe Harbor Provisions

[HN7] Under the Private Securities Litigation Reform Act of 1995, forward-looking statement only qualifies for the safe harbor to the extent that it is: (1) identified as a forward-looking statement, and is accompanied by meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the forward-looking statement 15 U.S.C.S. § 78u-5(c)(1)(A)(i); or (2) a plaintiff fails to prove the forward-looking statement was made, or approved by an executive officer of the company, with actual knowledge that the statement was false or misleading. 15 U.S.C.S. § 78u-5(c)(1)(B).

Securities Law > Liability > Disclosures > Forward Looking Statements

Securities Law > Liability > Securities Exchange Act of 1934 Actions > Express Liabilities > Misleading Statements > General Overview

[HN8] Regarding civil liability under the securities law, simply because material misrepresentations appear in the same document as a forward-looking statement does not make the statements of fact eligible for the safe harbor. In fact, one case states that if smaller non-forward-looking statements contained within the larger document are challenged as false, they fall outside the safe harbor.

Securities Law > Liability > Securities Exchange Act of 1934 Actions > Express Liabilities > Misleading Statements > General Overview

[HN9] Meaningful cautionary language in securities disclosures must be substantive and tailored to the specific predictions made in an allegedly misleading statement. A vague or blanket disclaimer which merely warns the reader that the investment has risks will ordinarily be inadequate to prevent misinformation.

Civil Procedure > Settlements > Releases From Liability > Interpretation of Releases

Securities Law > Liability > Disclosures > Bespeaks Caution Doctrine
Securities Law > Liability > Securities Exchange Act of 1934 Actions > Express Liabilities > Misleading Statements > General Overview
[HN10] In the context of disclosures in a securities offering, a defendant may not use cautionary language to protect himself when he is already aware that the risks he is cautioning against have come to fruition. Neither the safe harbor provision nor the bespeaks caution doctrine are applicable when defendants are aware of the facts that render their statements untrue when made.

Securities Law > Liability > Private Securities Litigation > General Overview
Securities Law > Liability > Securities Act of 1933 Actions > Civil Liability > Fraudulent Interstate Transactions > General Overview
Securities Law > Liability > Securities Exchange Act of 1934 Actions > Implied Private Rights of Action > Elements of Proof > Scienter > General Overview
[HN11] Scienter is a required element of a cause of action under the Securities and Exchange Act of 1934 and S.E.C. Rule 10b-5 promulgated thereunder. Scienter requires a plaintiff to prove that a defendant possessed a mental state embracing intent to deceive, manipulate or defraud. Since the adoption of the Private Securities Litigation Reform Act of 1995 a plaintiff's scienter allegations must create a reasonable and strong inference that the required intent is present.

Securities Law > Liability > Securities Act of 1933 Actions > Civil Liability > Fraudulent Interstate Transactions > General Overview
Securities Law > Liability > Securities Exchange Act of 1934 Actions > Implied Private Rights of Action > Elements of Proof > Scienter > Recklessness
Torts > Negligence > Standards of Care > Reasonable Care > General Overview
[HN12] A securities fraud plaintiff may plead scienter by alleging particular facts that are circumstantial evidence that a defendant has acted recklessly or with conscious disregard to the truth of his statement. A reckless statement is one made with not merely simple, or even inexcusable negligence, but an extreme departure from the standards of ordinary care, and which presents a danger of misleading buyers and sellers that is either known to a defendant or is so obvious that the actor must be aware of it.

Criminal Law & Procedure > Accusatory Instruments > Complaints
Securities Law > Liability > Securities Act of 1933 Actions > Civil Liability > Fraudulent Interstate Transactions > General Overview
Securities Law > Liability > Securities Exchange Act of 1934 Actions > Implied Private Rights of Action > Elements of Proof > Scienter > Recklessness
[HN13] In order to be held liable under S.E.C. Rule 10b-5 promulgated under the Securities Exchange Act of 1934, plaintiffs must clearly show that the defendants either are aware or should have been aware of the materiality of the facts they are misrepresenting.

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JUDGES: Clarence C. Newcomer, S.J.

OPINIONBY: Clarence C. Newcomer

OPINION: Newcomer, S.J.

I. Introduction

This is a class action securities fraud case against Viropharma and its officers. n1 Plaintiffs, purchasers of Viropharma Securities, claim that the Defendants made materially misleading statements regarding a drug that was developed by Viropharma called Pleconaril. They allege that these statements misled them as to whether Pleconaril would be approved by the Food and Drug Administration("FDA"). Eventually, the FDA rejected Pleconaril, and the company's stock plummeted. Currently before the Court is the Defendants' Motion to Dismiss the Consolidated Class Action Complaint.

n1 The individuals named include: Claude H. Nash, Viropharma's co-founder, Chairman of the Board, former Chief Executive Officer and former President; Michel de Rosen, Viropharma's current Chief Executive Officer and President; Mark A. McKinlay, Viropharma's co-founder and Vice President of Research and Development; and Vincent Milano, Viropharma's Chief Financial Officer.

[*3]

II. What a Court may Consider when Deciding a Motion to Dismiss

As a preliminary matter the Court must decide what materials are properly before it on the Defendants' Motion. Both sides have filed no less than four briefs arguing their respective positions. In support of these briefs, the Defendants submitted a total of forty-seven exhibits spread over four volumes and the Plaintiffs submitted several exhibits including the nine-page declaration of a Robert Makuch a biostatistician.

A. The Court Will Consider the Facts Alleged in the Complaint and Extrinsic Documents Either Explicitly Referenced in the Complaint or Integral to the Plaintiffs' Claims

[HN1] On a motion to dismiss, a court must accept all of the facts pleaded in the Plaintiffs' Complaint as true and take all reasonable inferences in favor of the Plaintiff. *Weston v. Pennsylvania, 251 F.3d 420, 425 (3d Cir. 2001)*. A court is not limited, however, to the four corners of the complaint. A court may consider any document that is explicitly relied upon in the complaint. *In re Burlington Coat Factory Sec. Lit., 114 F.3d 1410, 1426 (3d Cir. 1997)*. A court can also consider the text [*4] of an undisputedly authentic document that is integral to a plaintiff's claim, even if the document is not attached to or named in the complaint. Id. This prevents a plaintiff in a fraud case from pulling isolated statements from a document which may appear fraudulent, but are not so when viewed in context. Id. In such cases, a plaintiff is not able to prevent a court from considering the full text of the document just because the plaintiff chose not to attach it. *Id.* Accordingly, the Court will consider the Defendants' exhibits that were either referenced in, or integral to, the Plaintiffs' Complaint. n2

n2 These exhibits include the various press releases and other documents, which the Plaintiffs allege contain materially misleading statements. Although the Defendants did not submit all such documents, exhibits 11, 13, 16, 20, 24-28, and 31-33 were either explicitly referenced in the Plaintiffs' allegations or they are integral to the Plaintiffs claims.

B. The Court Will Not Consider Statements [*5] in Public Documents and Newspaper Articles for the Truth of the Matter Asserted Therein

[HN2] In addition to documents relied on by a plaintiff in the complaint, a court may can consider materials that are public records and that may be judicially noticed under *Federal Rule of Evidence 201. Oran v. Stafford, 226 F.3d 275, 289 (3d Cir. 2000)*. These materials, however, may only be considered for the limited purpose of showing that a particular statement was made by a particular person. They may not be considered for the truth of the matters stated within them.*Id.* (quoting *Kramer v. Time Warner, Inc., 937 F.2d 767, 774 (2d Cir. 1991)*. If a court adopted the approach of considering such documents for the truth of the matter asserted therein, it would be authorizing a trial by public documents, and thus imprudently expanding the scope of *12(b)(6)* motions.

Generally, this Court will not consider the public documents and newspaper articles submitted by the parties for the truth of the matter asserted in the documents. n3 Specifically, the Court will not accept as true the statements made by Viropharma in its SEC and FDA filings. It would be improper to [*6] accept these statements as true because the crux of the Plaintiffs' Complaint is that statements made by Viropharma were not truthful. In addition, the parties have submitted several public documents from the FDA which merely provide background on the process for testing and approving new drugs. n4 Unlike the statements of Viropharma, the authenticity and accuracy of these documents cannot reasonably be questioned. *Fed. R. Evid. 201(b)(2)*. In forming its opinion, the Court has relied on these documents only to this extent that they educate the Court in the FDA

approval process, but has not made any specific factual conclusions about this case based on them.

n3 These include Defendants' exhibits 6, 14, 18, 19, 22, 23, 29, and 34-37 and Plaintiffs' exhibits B to their Supplemental Submission in Opposition to Defendants Motion to Dismiss.

n4 These include Defendants exhibits 1-5 ,7-10, 39, 40, 42-46, exhibits A and C to the Plaintiffs' Motion to Strike, and Plaintiffs exhibits C-G to the Plaintiffs' Supplemental Submission in Opposition to the Defendants' Motion to Dismiss.

[*7]

C. Other Documents Submitted by the Parties

The parties have also submitted several other documents that are not proper on a motion to dismiss. The Plaintiffs' submission of an expert report at this stage is entirely improper. *DeMarco v. DepoTech Corp., 149 F. Supp. 2d 1212, 1219-22 (S.D. Cal. 2001)*; See Visconti by Visconti v. United States Healthcare, 1998 U.S. Dist. LEXIS 15691 at *12 (E.D.Pa. Sept. 28, 1998)(expert report is not a pleading). Besides being wholly outside of the pleadings, this expert report attempts to circumvent the usual procedures for allowing expert testimony. See *DeMarco, 149 F. Supp. 2d at 1221*. The Defendants have not had the opportunity to examine Mr. Makuch or to challenge his qualifications and the methodology of his opinions. The Defendants have also submitted several documents that are neither suitable for judicial notice, nor integral to the Plaintiffs' Complaint. These documents will not be considered.

II. Factual Background

A. Background on the FDA Approval Process

Every drug sold in the United States must first be approved by the FDA. Approval by the FDA requires preclinical [*8] trials usually done on animals, then at least three phases of clinical trials on humans (these trials are referred to as phases I, II, and III). Phase I trials are mainly aimed at determining if the metabolic and pharmacologic actions of the drug in humans are safe enough to proceed to Phase II studies. Phase II studies are controlled clinical studies that involve a limited population infected with the disease the drug proposes to treat. Phase III studies usually involve many more people than Phase II studies and are intended to gather additional information on the drug's efficacy and safety that will be used in evaluating its overall risks and benefits.

After the completion of Phase III clinical trials, the drug company files a New Drug Application(NDA) with the FDA. A NDA should present information regarding the sub-groups that will eventually comprise the drug's market. If the application is not sufficient, the FDA will refuse to file it. If the NDA is accepted, the FDA may refer the application to an advisory committee of outside experts. The recommendations of these committees are not binding, but are almost universally followed. After making its decision, the FDA sends one of [*9] three letters: an approval letter, a not approvable letter, or an approvable letter.

B. History of Pleconaril

Pleconaril is a drug aimed at treating picornaviruses. Picornaviruses are the cause of over one-half of all common colds. Pleconaril was the first drug that was ever submitted to the FDA for the treatment of these viruses. The predicted affect of the drug was to shorten the duration of colds in adults.

Viropharma ran clinical trials on Pleconaril from the early 1990s until the rejection of the drug by the FDA in 2002. On July 13, 1999, Viropharma announced the results of one of its Phase II studies. Contrary to the statements made by Viropharma, the Plaintiffs allege that this study and all other Phase II trials showed no statistically significant effect. On April 11, 2000, Viropharma announced that a Phase III study had failed to show any significant treatment benefit. Despite these studies, however, Viropharma announced on March 15, 2001, that a later Phase III study had proven successful.

The Plaintiff alleges that this later Phase III study was lacking in several respects. First, the study showed that the drug had a negative impact on smokers. This negative effect [*10] was confirmed in three different trials. Also, those suffering from heart problems and other co-morbid conditions were wholly excluded from the study. Third, because minorities and the elderly were underrepresented no conclusions could be made about the drug's efficacy and safety in these groups. The Plaintiffs also allege that Pleconaril did not show a significant treatment effect in the male population. Because of these deficiencies, the Plaintiffs allege that the therapeutic profile for Pleconaril was extremely narrow, and therefore Defendants could not claim that it was marketable to all adults.

In the fall of 2001, after Viropharma submitted the NDA for Pleconaril, Viropharma did a six-week prophylaxis study to confirm the drug's efficacy and test the safety of the drug when interacting with other medications. This was the first time Viropharma had tested Pleconaril's interaction with other drugs. In this trial, several women who were taking oral contraceptives experienced menstrual difficulties. Although the preliminary results of the study were available to Viropharma by mid-February 2002, they were not released to the public until

March 18, 2002. This study spurred Viropharma [*11] to undertake other studies to explore the side effects of Pleconaril, but before these studies were completed the FDA's Advisory committee rejected Pleconaril. The FDA sent a non-approval letter to Viropharma on May 30, 2002.

C. Allegedly Misleading Statements

The Plaintiffs allege that several public statements made during the course of the clinical trial and approval process were material misrepresentations. These were statements made both by the Defendants directly and by analysts on behalf of the company. The crux of the Plaintiffs' Complaint is that these statements represented to the investing public that Pleconaril was effective at reducing the common cold, and that it was effective over the whole spectrum of adults. The statements are:

1) A July 13, 1999, press release stating that the Phase II trials were a success. In this release Viropharma stated that "Pleconaril-treated patients experienced a clinically and statistically significant reduction in time to complete resolution of all disease symptoms, as well as a reduction in the patient-reported time to return to feeling normal." n5

2) A February 24, 2000 report in the Dow Jones Newswire repeated the statements [*12] of Defendant Milano that "Pleconaril is a very exciting product. . . . We have received a lot of interest from pharmaceutical companies."

3) A February 28, 2001, issue of Bioworld published an interview with a Viropharma spokeswoman who stated that after reviewing previous clinical trials, the Company "took several steps to try to increase the likelihood of success."

4) A March 15, 2001, interview with Defendant de Rosen stated that Pleconaril "will probably be good for either everybody or close to everybody" and that it should reach approximately two-thirds of the colds in America. n6

5) A March 15, 2001, report by analysts based on information disseminated by the Defendants stated that the company believed "that Pleconaril's benefit, consistent across endpoints and between studies, puts it on a strong approval track as the first and only drug candidate to effectively treat the cause and symptoms of VRI. VRI results in 34 million U.S. physician visits each year."

6) Defendant de Rosen stated in March of 2001 that the completion of clinical studies was a "truly momentous event in our history." He also claimed that the achievement was all that more remarkable because [*13] Viropharma had been forced to completely reshape its clinical program after three successive studies had produced negative results. n7

7) On August 24, 2001, Defendants represented that non-smokers simply "experienced greater reduction in duration." Smokers who were treated with the drug actually had the duration of their colds extended.

8) On October 19, 2001 Form 8-K filed with the SEC stated that Viropharma had submitted a NDA requesting permission to market Picovir for the treatment of VRI in adults.

n5 Viropharma made several similar statements touting the efficacy of Pleconaril. An August 14, 2000, statement in the Wall Street Journal claimed that: "In clinical studies to date, Pleconaril - treated patients have experienced a shortening in their disease duration and a decrease in the severity of their disease." A March 15, 2001, press release stated that results from clinical studies "demonstrated that patients with a VRI caused by picornavirus who were treated with Pleconaril experienced a statistically significant decrease in disease duration and in cold symptom severity." Defendant McKinlay was quoted in April 9, 2001, as saying that certain clinical studies showed that patients experienced a reduction in the severity and duration of their illness. Similar statements were also included in an allegedly misleading analyst report dated August 24, 2001 and an October 8, 2001, Morgan Stanley Dean Witter report based on a Viropharma presentation.

[*14]

n6 Similarly, Defendant de Rosen allegedly exaggerated the scope of Pleconaril in an April 30, 2001, letter to stockholders by stating that every person is a potential patient and that millions of patients need the drug. In a Barron's article on May 7, 2001, he stated that "we need to market this as a scientific revolution because this is a disease that anyone can catch. Potentially every family in America could use it." On September 10, 2001, in discussing the collaboration between Viropharma and Aventis Pharmaceutical, the Company stated that the agreement "clearly represents a tremendous opportunity to potentially reach patients and physicians. The common cold is the number one reason for physician visits in the Unities States today."

n7 Defendant de Rosen also referred to the success of certain trials as a momentous event in an April 30, 2001, letter to stockholders. Similarly, Defendant Milano was quoted as saying that "we believe this is going to be successful, and we're very passionate about making it happen."

D. Viropharma's Securities

Viropharma's stock price rose and fell [*15] on the hopes for FDA approval for Pleconaril. When Viropharma announced that its July 13, 1999, Phase II study was a success, the company's stock rose from $ 9.25 to $ 19.13 per share. Two months later, the company announced a sale of three million shares of stock priced at nineteen dollars a share. In February of 2000, the Defendants announced the intent to issue one-hundred-and-fifty million dollars in convertible subordinated notes.

When the prospects for the success of Pleconaril deteriorated, so did the stock price of Viropharma. When the disappointing Phase III study results were announced on April 11, 2000, the share price of Viropharma dropped from $ 71.75 to $ 23.25 per share. When the Advisory Committee recommended that the drug not be approved, the share price dropped from $ 5.50 to $ 1.41. After Viropharma received the non-approval letter for Pleconaril, the stock dropped to a few pennies per shares.

III. Discussion

A. Securities Fraud Claims under Section 10(b) of The Securities Exchange Act and Rule 10b-5

The Complaint sets forth allegations against the Defendants under *Section 10(b) of the Securities Exchange Act of 1934* and *Rule 10b-5* promulgated thereunder [*16] by the S.E.C. [HN3] To state a claim under *Rule 10b-5*, the plaintiff needs to plead that: 1) the defendant made a materially false or misleading statement or omitted a material fact necessary to make a statement not misleading; 2) the statement was made in connection with the sale of securities; 3) the statement was made with scienter; 4) the plaintiff reasonably relied on the statement; and, 5) the misstatement proximately caused the plaintiff's injury. n8 *Oran v. Stafford, 226 F.3d 275, 282 (3d Cir. 2000).*

n8 Although the Defendants state that the complaint does not meet any of these elements, they only offer argument on elements one and three. After evaluating the Plaintiff's Complaint, the Court concludes that it pleads sufficient facts to satisfy elements two, four, and five.

B. While the Defendants' have Correctly Stated that They had no Duty to Predict the Advisory Committee's Decision, They did have a Duty not to Make Material Misstatements of Fact

The Defendants claim that the Plaintiffs [*17] are seeking to impose a duty to predict the outcome of the FDA's decision. They further argue that they had no such duty under the securities laws. The Court soundly agrees that 10b-5 does not place an obligation to predict the FDA's decision. The thrust of the Plaintiffs' Complaint, however, is not seeking to impose such a duty. n9

n9 One paragraph of the Plaintiffs' Complaint does allege that Viropharma materially misled investors by saying the Pleconaril was on the track to FDA approval. The Court finds this statement to be immaterial. See Section IV(D), infra.

The Plaintiff is alleging that the Defendants breached their duty to not make material misstatements. Whether the Defendants had to predict the FDA's decision is irrelevant. They are liable under 10b-5 if they made statements that a reasonable investor would consider in deciding whether to buy stock. All investing is based on investors' perceptions about the future. The Plaintiffs in this case bought Viropharma securities based on their perception [*18] of whether Pleconaril would be approved by the FDA. Viropharma would not be responsible if its investors' perceptions were based solely on the company's predictions about the prospects for FDA approval. That is not the case, however. Rather the allegations in this case are that Viropharma made misstatements of fact which formed the basis for its investors' perceptions. See In Re NAHC, Inc. Sec. Litig., 2001 U.S. Dist. LEXIS 16754 at *35 (E.D. Pa. Oct. 17,

2001)(stating that while corporate officials do not need to be clairvoyant, they are responsible for revealing material facts known to them). Accuracy in these types of factual statements lies at the heart of what the securities laws are trying to protect.

C. The Defendants did have a Duty to not Materially Mislead the Market when Making Statements About Pleconaril's Efficacy

The Defendants argue that the failure to disclose efficacy data that was not considered fatal by the FDA does not render alleged statements materially misleading. In making this argument, the Defendants are asking the Court to make a determination as to the basis of the FDA's decision to deny the NDA for Pleconaril. At this stage in the [*19] litigation, it is simply not within the Court's purview to make such a determination. In re Cell Pathways Inc. Sec. Litig., 2000 U.S. Dist. LEXIS 8584 at *28 (E.D.Pa. June 21, 2000)(holding that on a motion to dismiss it is inappropriate to dismiss a complaint based merely on a defendant's "insistence on their version of the contested issues in the case").

D. The Defendants may have had a Duty to Disclose Drug Interaction Data

The Defendants claim that they had no duty to disclose drug interaction data from the six-week prophylaxis study conducted in late 2001. The Defendants argue that this information was preliminary and could not have altered the total mix of information in the market. [HN4] Drug interaction data that is not statistically significant need not be disclosed in order to prevent prior statements about a drug's safety from becoming materially misleading. *Oran v. Stafford, 226 F.3d 275, 284 (3d Cir. 2000)*. At this stage in the litigation, however, the Court is unable to determine whether the data from the six-week study was statistically significant, and therefore, the Court must reject this argument.

E) Materiality of the Alleged [*20] Misrepresentations

[HN5] Only misrepresentations that are material are actionable. The test for determining the materiality of a statement is whether a reasonable investor would believe that it "significantly alters the 'total mix' of information' available to that investor." *Oran v. Stafford, 226 F.3d 275, 282 (3d Cir. 2000)*(citing *In re Westinghouse Sec. Litig., 90 F.3d 696, 714 (3d Cir. 1996))*. Certain types of "soft information" such as statements of subjective opinions and intentions are immaterial as a matter of law. *In re Craftmatic Sec. Litig., 890 F.2d 628, 642 (3d Cir. 1989)*. Similarly, the law considers vague and general statements of optimism as mere immaterial puffery. *In re Advanta Corp. Sec. Litig., 180 F.3d 525 (3d Cir. 1999)*. To determine whether a statement is puffery, a court must examine the context in which the statement was made. *In re Lucent Technologies, Inc. Sec. Litig., 2002 U.S. LEXIS 11556 at *77 (D.N.J. June 26, 2002)*. Classic examples of puff include a broker calling a bond "marvelous," or saying a stock is so "red hot" that the investor "could not lose." *Newman v. L.F. Rothschild, 651 F. Supp. 160, 163 (S.D.N.Y. 1986)*. [*21]

Several of the Defendants' allegedly actionable statements are not material under the above legal analysis. The statements concerning the potential scope of Pleconaril, cited in Section 2(C)(4) above, like "everybody is potential patient" and referring to Pleconaril as "a scientific revolution," are simply not the type of factual statements upon which reasonable investors base their decisions. Similarly, the statements referring to successful clinical trials as a momentous event in Viropharma's history (Sec. II(C)(6) supra) and the February 24, 2000, quote from the Dow Jones Newswire describing Pleconaril as a "very exciting product" (Sec. II(C)(2) supra) must be dismissed as mere puffing. The March 15, 2001, report that merely stated the company's belief that Pleconaril was on a strong track to approval (Sec. II(C)(5) supra) is also immaterial because investors should not rely on a company's prediction about the future actions of independent government agencies. n10 See *Epstein v. Washington Energy Co., 83 F.3d 1136, 1142 (9th Cir. 1996)*(finding no duty to predict action of public utility commission); Fanni v. Northrop Grumman Corp., 2000 Dist. LEXIS 21626, [*22] at *32-37 (C.D. Cal. April 10, 2000)(finding no duty to predict whether Department of Justice would approve merger).

n10 The Court also notes that the allegedly misleading statement made in the February 28, 2001, issue of Bioworld (Sec. II (C)(3) above) is also not actionable. The statement only conveys the fact that Viropharma redesigned its clinical trials in an attempt to increase the likelihood of success. The Plaintiffs, however, have not pleaded that Viropharma did not redesign its clinical trials. Accordingly, the Complaint does not state sufficient facts to impose 10-b5 liability on the basis of this statement.

The remainder of the alleged statements cannot be disregarded as puffery or subjective opinions. Statements regarding the overall efficacy of the drug, the claim that smokers received a decreased benefit when in fact the data showed the drug extended the duration of their colds, and statements that the NDA for Pleconaril was aimed at seeking approval for all adults, cannot be simply dismissed [*23] as immaterial as the Defendants claim. Indeed, it would be sad day when court could de-

termine that misstatements about a whether a company's primary product worked did not alter the 'total mix' of information available in the market. This is not a case where the Plaintiffs claim that the absence of information about a product renders a statement materially misleading. See *In re PLC Sys., Inc. Sec. Litig., 41 F. Supp. 2d 106, 115-16 (D.Mass. 1999)* (finding that merely disclosing one fact about a product does not require the disclosure of all facts that may be of interest to the market). Rather, the Plaintiffs have pleaded that the statements made by Defendants were contrary to the then existing state of facts, for example, that Pleconaril was effective for all adults when it was not.

F) The Safe Harbor for Forward-Looking Statements

[HN6] The Private Securities Litigation Reform Act of 1995 (hereinafter "PSLRA") provides a safe harbor for forward-looking statements. A forward looking statement is one whose truth or falsity cannot be determined until after the statement has been made. *Harris v. Ivax Corp., 182 F.3d 799, 805 (11th Cir. 1999)*. Forward [*24] looking statements include: (1) "a statement containing a projection of revenues" or other financial items; (2) "a statement of the plans and objectives of management for future operations, including plans or objectives relating to the products or services of the issuer;" (3) "a statement of future economic performance;" and (4) "any statement of the assumptions underlying or relating" to the aforementioned statements. *15 U.S.C. § 78u-5(i)(1)*. Additionally, [HN7] A forward-looking statement only qualifies for the safe harbor to the extent that it is:

> (1) "identified as a forward-looking statement, and is accompanied by meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the forward-looking statement" (*15 U.S.C. § 78u-5(c)(1)(A)(i)*);
>
> or
>
> (2) the plaintiff fails to prove the forward-looking statement was made, or approved by an executive officer of the company, with actual knowledge that the statement was false or misleading. (*15 U.S.C. § 78u-5(c)(1)(B)*).

1) The Statements found by the Court to be Material Misrepresentations [*25] are not Forward-Looking n11

n11 Because the Court has determined that the other four statements alleged by the Defendants to be forward-looking are not actionable because they are not material, the Court will not discuss whether they qualify for the safe harbor.

The Court finds that the material misrepresentations in the July 13, 1999, press release n12 and in the October 19, 2001 8-K Filing under the heading "Have you submitted an NDA for Picovir(TM)?" are not forward-looking. n13 They do not fall into any of the categories of forward-looking statements listed above. Rather, these statements when read in the context are statements conveying to the market the current status of clinical trials and the NDA for Pleconaril. The truth or falsity of both of these statements was determinable at the time they were made.

n12 The challenged sections of this press release are as follows:

> Trial results indicate that Pleconaril-treated patients experienced a clinically and statistically significant reduction in time to complete resolution of all disease symptoms, as well as a reduction in the patient-reported time to returning to feeling normal, as measured by a global assessment score. . . . We've seen excellent results with Pleconaril in patients with viral respiratory infection, a disease for which there are no available antiviral treatments. Our plan is to continue the path towards regulatory approval of this important new therapy.

[*26]

n13 In the 2001 8-K Filing, the Plaintiffs challenge the same statement-- "we submitted an NDA to the FDA requesting permission to market Picovir for the treatment of VRI in adults-- which appears under two different headings. The first heading-- "What will be the primary indication for Picovir(TM)?"-- could render the first resuscitation of the above quote forward-looking. The heading asking specifically about whether the Defendants had submitted a NDA, however, is clearly a statement of fact, and therefore, does not

qualify for protection under the safe harbor. Accordingly, whether the first statement does or does not qualify for the safe harbor is irrelevant.

In their argument, the Defendants pull isolated forward-looking statements out of the documents at issue in this case. The Defendants do not point out, however, that included in these documents are assertions of then-existing fact. The Plaintiffs are not alleging that the forward-looking portions of the documents are false and misleading, but instead point to the statements of fact. [HN8] Simply because material misrepresentations appear in [*27] the same document as a forward-looking statement does not make the statements of fact eligible for the safe harbor. In fact, the very case on which the Defendants rely, *Harris v. Ivax Corp., 182 F.3d 799 (11th Cir. 1999)*, stated that if smaller non-forward-looking statements contained within the larger document are challenged as false, it is easily concluded that they fall outside the safe harbor. *Harris, 182 F.3d at 806*. See, also, *In re Penn Treaty American Corp. Sec. Litig., 202 F. Supp. 2d 383, 393 (E.D.Pa. 2002)*(rejecting a defendants' attempt to pull isolated forward-looking portions out of a document while ignoring the statement of fact).

2) The July 13, 1999, Press Release and The October 19, 2001 8-K Filing do Not Include Meaningful Cautionary Language

Even if the two material misrepresentations discussed above were forward looking, they would not qualify for the safe harbor because they are not accompanied by meaningful cautionary language as required by *15 U.S.C. § 78u-5(c)(1)(A)(i)*. n14 [HN9] Meaningful cautionary language must be substantive and tailored to the specific predictions made in the [*28] allegedly misleading statement. *In re Donald J.Trump Casino Sec. Litig., 7 F.3d 357, 371-372 (3d Cir. 1993)*. "A vague or blanket disclaimer which merely warns the reader that the investment has risks will ordinarily be inadequate to prevent misinformation." *Id.*

n14 The Court also finds that the second part of the safe-harbor, that the Plaintiffs must have failed to allege that the statements were made with actual knowledge of their falsity is not met. As explained in the discussion of scienter Section IV(E), infra., the Plaintiffs did plead that the these statements were made with actual knowledge of their falsity.

The language that the Defendants cite as cautionary is verbose, and more importantly it falls far short of advising investors about any specific risks. This language would not discourage reliance on the statements of fact in the July 13, 2000, press release and the Form 8-k. The "cautionary language" in the July 13 press release only states that future clinical trials may fail, [*29] this does not caution investors that the results of the clinical trial reported in the press release could be interpreted to show that the drug was ineffective. Moreover, [HN10] a defendant may not use cautionary language to protect himself when he is already aware that the risks he is cautioning against have come to fruition. In re Cell Pathways, Inc. Sec. Litig., 2000 U.S.Dist. LEXIS 8584 (E.D. Pa. June 21, 2000); see, also, *In re World Access, Inc. Sec. Litig., 119 F. Supp. 2d 1348 (N.D.Ga. 2000)*("Neither the safe harbor provision nor the bespeaks caution doctrine are applicable when defendants are aware . . . of the facts that render their statements untrue when made").

E) The Plaintiffs' Pleadings have Created a Reasonable and Strong Inference of Scienter

[HN11] Scienter is a required element of a cause of action under the *Securities and Exchange Act of 1934* and *Rule 10b-5*. Scienter requires a plaintiff to prove that a defendant possessed a mental state embracing intent to deceive, manipulate or defraud. *Ernst and Ernst v. Hochfelder, 425 U.S. 185, 47 L. Ed. 2d 668, 96 S. Ct. 1375 (1976)*. Since the adoption of the PSLRA, a plaintiff's [*30] scienter allegations must create a reasonable and strong inference that the required intent is present. *In re Advanta Corp. Securities Litigation, 180 F.3d 525, 534-35 (3d Cir. 1999)*.

[HN12] A plaintiff may plead scienter by alleging particular facts that are circumstantial evidence that a defendant acted recklessly or with conscious disregard to the truth of his statement. *Advanta, 180 F.3d at 534-5*. A reckless statement is one made with "not merely simple, or even inexcusable negligence, but an extreme departure from the standards of ordinary care, and which presents a danger of misleading buyers and sellers that is either known to the Defendant or is so obvious that the actor must be aware of it." *Mclean v. Alexander, 599 F.2d 1190, 1197 (3d Cir. 1979)*(quoting *Sudstrand Corp. v. Sun Chem. Corp., 553 F.2d 1033, 1045 (7th Cir. 1977)*.

The Plaintiffs have sufficiently alleged that the Defendants either knew that their statements were false or acted with reckless disregard for the truth of those statements. According to the allegations in the Plaintiffs' Complaint, the Defendants were aware of the lack of efficacy shown [*31] by the Phase II trials, the lack of sufficient data to make any conclusions regarding the efficacy and safety of Pleconaril in significant subgroups, and the negative drug interaction between Pleconaril and oral contraceptives. Knowledge of these facts can be imputed to the Defendants for several reasons. First, because Pleconaril was Viropharma's leading prod-

uct and Defendants were the highest ranking members of the company, it can be assumed that the Defendants were aware of these facts. See *In re Aetna Sec. Litig., 34 F. Supp. 2d 935, 953 (E.D.Pa. 1999)*; In re Tel-Save Sec. Litig., 1999 U.S. Dist. LEXIS 16800 at *14 (E.D. Pa. 1999); *Epstein v. Itron, Inc., 993 F. Supp. 1314, 1326 (E.D. Wash. 1998)*. Second, because of the Defendants' positions in the company they had access to several documents which contained the facts that allegedly made the Defendants' statements materially misleading. See *In re Campbell Soup Co. Sec. Litig., 145 F. Supp. 2d 574, 599 (D.N.J. 2001)*(stating that a claim of recklessness can be based on allegations that defendants had access to information which contradicted their public statements). [*32] Here the Defendants had access to non-public annual reports which contained the results of the clinical trials, the NDA for Pleconaril which contained data from the Phase II and III trials, and the Case Report Forms prepared during the clinical trials. It is even more clear that the Defendants were aware of data that contradicted their statements regarding subgroups because the FDA mandated that data be reported separately based on age and race. Further, the harmful effect on smokers was evident to the Defendants because smokers were stratified in the Phase III trails. Based on these allegations, the Court concludes that there is strong and reasonable inference that the Defendants knew their statements were misleading or that they acted with an extraordinary lack of care when making the statements.

The Defendants argue that the Complaint lacks sufficient allegations of scienter based on recklessness because the Defendants were not aware of the materiality of their statements. [HN13] In order to be held liable under 10b-5, the plaintiffs must clearly show that the Defendants either were aware or should have been aware of the materiality of the facts they were misrepresenting. See *City of Phila. V. Fleming Cos., 264 F.3d 1245, 1261 (10th Cir. 2001)*. [*33] The Defendants once again attempt to argue that they could not have known their statements were material because the FDA usually considers drug interaction and subgroup limitations as labeling issues and not barriers to approval. Again, the Defendants ignore the reality of Plaintiffs' decision to buy Viropharma stock. In making this decision, the efficacy of the drug in general and in large subgroups is obviously material.

V. Conclusion

For the reasons stated above, the Defendants' Motion to Dismiss the Consolidated Class Action Complaint is granted in part and denied in part. An appropriate Order will follow.

Clarence C. Newcomer, S.J.

Order

AND NOW, this 3rd day of April, 2003, upon consideration of the Defendants' Motion to Dismiss the Consolidated Class Action Complaint (Doc. 14), and responses thereto, it is hereby ORDERED that said Motion is GRANTED in part, and DENIED in part. It is further ORDERED that Paragraphs 45, 46, 57-59, 61, and 62 are hereby STRICKEN from the Plaintiff's Complaint.

AND IT IS SO ORDERED.

/s/

Clarence C. Newcomer, S.J.